



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Michael A. Apicella et al. Art Unit : 1642
Serial No. : 10/665,990 Examiner : Unknown
Filed : September 19, 2003
Title : VACCINE AND COMPOSITIONS FOR THE PREVENTION AND
TREATMENT OF NEISSERIAL INFECTIONS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL

The following correspondence relating to this application is enclosed for filing:

1. Information Disclosure Statement (1 page);
2. Form PTO-1449 (10 pages);
3. Copies of Cited References (181 references); and
4. A Return Postcard.

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Respectfully submitted,

Date: 27 July 2004

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Lisa M. Becker
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INFORMATION DISCLOSURE STATEMENT

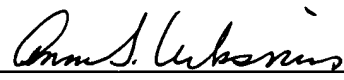
Applicant submits the references listed on the attached form PTO-1449.

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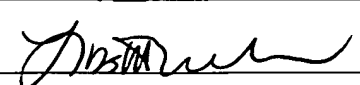

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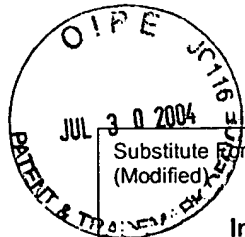
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Substitute Form PTO-1449 (Modified)	U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 17023-031001	Application No. 10/665,990
Information Disclosure Statement by Applicant (Use several sheets if necessary) (37 CFR §1.98(b))		Applicant Michael A. Apicella et al.	
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U.S. Patent Documents							
Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	4,533,630	08/06/85	Wilkins et al.			
	AB	4,554,101	11/19/85	Hopp			
	AC	4,559,157	12/17/85	Smith et al.			
	AD	4,608,392	08/26/86	Jacquet et al.			
	AE	4,820,508	04/11/89	Wortzman			
	AF	4,873,192	10/10/89	Kunkel			
	AG	4,938,949	07/03/90	Borch et al.			
	AH	4,992,478	02/12/91	Geria			

Foreign Patent Documents or Published Foreign Patent Applications								
Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AI	0 184 187	06/11/86	EPO				
	AJ	WO 99/24578	05/20/99	PCT				
	AK	WO 99/57280	11/11/99	PCT				
	AL	WO 98/02547	01/20/98	PCT				
	AM	WO 00/71725	11/30/00	PCT				

Other Documents (include Author, Title, Date, and Place of Publication)		
Examiner Initial	Desig. ID	Document
	AN	GenBank Accession Number B81859
	AO	Alpuche-Aranda et al., "Salmonella Stimulate Macrophage Macropinocytosis and Persist within Spacious Phagosomes," <u>J. Exp. Med.</u> , 1994, 179:601-608
	AP	Altieri, "Occupancy of CD11b/CD18 (Mac-1) Divalent Ion Binding Site(s) Induces Leukocyte Adhesion," <u>J. Immunol.</u> , 1991, 147:1891-1898
	AQ	Altschul et al., "Basic Local Alignment Search Tool," <u>J. Mol. Biol.</u> , 1990, 215:403-410
	AR	Altschul et al., "Gapped BLAST and PSI-BLAST: a new generation of protein database search programs," <u>Nucl. Acids Res.</u> , 1997, 25:3389-3402
	AS	Apicella, "Antigenically Distinct Populations of <i>Neisseria gonorrhoeae</i> : Isolation and Characterization of the Responsible Determinants," <u>J. Infect. Dis.</u> , 1974, 130:619-625
	AT	Batzer et al., "Enhanced evolutionary PCR using oligonucleotides with inosine at the 3'-terminus," <u>Nucl. Acids. Res.</u> , 1991, 19:5081

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	AU	Becherer et al., "Cell Surface Proteins Reacting with Activated Complement Components," <u>Complement Inflamm.</u> , 1989, 6:142-165
	AV	Bessen and Gotschlich, "Interactions of Gonococci with HeLa Cells: Attachment, Detachment, Replication, Penetration, and the Role of Protein II," <u>Infect. Immun.</u> , 1986, 54:154-160
	AW	Bjerknes et al., "Neisserial Porins Inhibit Human Neutrophil Actin Polymerization, Degranulation, Opsonin Receptor Expression, and Phagocytosis but Prime the Neutrophils To Increase Their Oxidative Burst," <u>Infect. Immun.</u> , 1995, 63:160-167
	AX	Cann et al., "Detection of antibodies to common antigens of pathogenic and commensal <i>Neisseria</i> species," <u>J. Med. Microbiol.</u> , 1989, 30:23-30
	AY	Caron et al., "Identification of Two Distinct Mechanisms of Phagocytosis Controlled by Different Rho GTPases," <u>Science</u> , 1998, 282:1717-1721
	AZ	Carrea et al., "Purification and properties of two phospholipases D from <i>Streptomyces</i> sp.," <u>Biochim. Biophys. Acta.</u> , 1995, 1255:273-279
	AAA	Chen et al., "Heparin Protects Opa ⁺ <i>Neisseria gonorrhoeae</i> from the Bactericidal Action of Normal Human Serum," <u>Infect. Immun.</u> , 1995, 63:1790-1795
	ABB	Christodoulides et al., "Interaction of primary human endometrial cells with <i>Neisseria gonorrhoeae</i> expressing green fluorescent protein," <u>Mol. Microbiol.</u> , 2000, 35:32-43
	ACC	Clarke and Spudich, "Nonmuscle Contractile Proteins: The Role of Actin and Myosin in Cell Motility and Shape Determination," <u>Ann. Rev. Biochem.</u> , 1977, 46:797-822
	ADD	Clauser et al., "Role of Accurate Mass Measurement (± 10 ppm) in Protein Identification Strategies Employing MS or MS/MS and Database Searching," <u>Anal. Chem.</u> , 1999, 71:2871-2882
	AEE	Clerc and Sansonetti, "Entry of <i>Shigella flexneri</i> into HeLa Cells: Evidence for Directed Phagocytosis Involving Actin Polymerization and Myosin Accumulation," <u>Infect. Immun.</u> , 1987, 55:2681-2688
	AFF	Cohen et al., "Human Experimentation with <i>Neisseria gonorrhoeae</i> : Rationale, Methods, and Implications for the Biology of Infection and Vaccine Development," <u>J. Infect. Dis.</u> , 1994, 169:532-537
	AGG	Colley et al., "Phospholipase D2, a distinct phospholipase D isoform with novel regulatory properties that provokes cytoskeletal reorganization," <u>Curr. Biol.</u> , 1997, 7:191-201
	AHH	Cooper, "Complement evasion strategies of microorganisms," <u>Immun. Today</u> , 1991, 12(9):327-331
	AII	Corpet, "Multiple sequence alignment with hierarchical clustering," <u>Nucl Acids Res.</u> , 1988, 16:10881-10890
	AJJ	Dayhoff et al., "A Model of Evolutionary Change in Proteins," <u>Atlas of Protein Sequence and Structure</u> , Natl. Biomed. Res. Found., 1978, pp. 345-352
	AKK	de la Paz et al., "Effect of sialylation of lipopolysaccharide of <i>Neisseria gonorrhoeae</i> on recognition and complement-mediated killing by monoclonal antibodies directed against different outer-membrane antigens," <u>Microbiology</u> , 1995, 141:913-920
	ALL	Dehio et al., "The role of neisserial Opa proteins in interactions with host cells," <u>Trends Microbiol.</u> , 1998, 6:489-495
	AMM	Densen et al., "Dissemination of Gonococcal Infection is Associated with Delayed Stimulation of Complement-Dependent Neutrophil Chemotaxis In Vitro," <u>Infection and Immunity</u> , 1982, 38:563-572

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	ANN	DiPaolo et al., "Cellular and Molecular Alterations in Human Epithelial Cells Transformed by Recombinant Human Papillomavirus DNA," <u>Crit. Rev. Oncogen.</u> , 1993, 4:337-360
	AOO	Dramsai and Cossart, "Intracellular Pathogens and the Actin Cytoskeleton," <u>Annu. Rev. Cell Dev. Biol.</u> , 1998, 14:137-166
	APP	Draper et al., "Scanning electron microscopy of attachment of <i>Neisseria gonorrhoeae</i> colony phenotypes to surfaces of human genital epithelia," <u>Am. J. Obstet. Gynecol.</u> , 1980, 138:818-826
	AQQ	Dudas and Apicella, "Selection and Immunochemical Analysis of Lipooligosaccharide Mutants of <i>Neisseria gonorrhoeae</i> ," <u>Infect. Immun.</u> , 1988, 56:499-504
	ARR	Edwards and Apicella, "The role of lipooligosaccharide in <i>Neisseria gonorrhoeae</i> pathogenesis of cervical epithelia: lipid A serves as a C3 acceptor molecule," <u>Cell. Microbiol.</u> , 2002, 4:585-598
	ASS	Edwards et al., "A co-operative interaction between <i>Neisseria gonorrhoeae</i> and complement receptor 3 mediates infection of primary cervical epithelial cells," <u>Cell. Microbiol.</u> , 2002, 4:571-584
	ATT	Edwards et al., "Complement Receptor Type 3 (CR3) on Primary Cervical Epithelial Cells Serves as a Receptor for <i>Neisseria Gonorrhoeae</i> ," Abstracts of the 101 st General Meeting of the American Society for Microbiology, 2001, Orlando, FL, p. 303
	AUU	Edwards et al., "The Role of Complement Receptor 3 (CR3) in <i>Neisseria Gonorrhoeae</i> Infection of Human Cervical Epithelia," <u>Cell. Microbiol.</u> , 2001, 3:611-622
	AVV	Elemer and Edgington, "Microfilament Reorganization Is Associated with Functional Activation of $\alpha_4\beta_2$ on Monocytic Cells," <u>J. Biol. Chem.</u> , 1994, 269:3159-3166
	AWW	Erdei et al., "The role of C3 in the immune response," <u>Immun. Today</u> , 1991, 12:332-337
	AXX	Evans, "Ultrastructural Study of Cervical Gonorrhea," <u>J. Infect. Dis.</u> , 1977, 136(2):248-255
	AYY	Exton, "New Developments in Phospholipase D," <u>J. Biol. Chem.</u> , 1997, 272:15579-15582
	AZZ	Fällman et al., "Complement Receptor-mediated Phagocytosis Is Associated with Accumulation of Phosphatidylcholine-derived Diglyceride in Human Neutrophils," <u>J. Biol. Chem.</u> , 1992, 267:2656-2663
	AAAA	Fijen et al., "The role of Fc γ receptor polymorphisms and C3 in the immune defense against <i>Neisseria meningitidis</i> in complement-deficient individuals," <u>Clin. Exp. Immunol.</u> , 2000, 120:338-345
	ABBB	Finlay and Falkow, "Common Themes in Microbial Pathogenicity Revisited," <u>Microbiol. Mol. Biol. Rev.</u> , 1997, 61:136-169
	ACCC	Finlay and Ruschkowski, "Cytoskeletal rearrangements accompanying <i>Salmonella</i> entry into epithelial cells," <u>J. Cell Sci.</u> , 1991, 99:283-296
	ADDD	Fluhmann, "The Squamocolumnar Transitional Zone of the Cervix Uteri," <u>Obstet. Gynecol.</u> , 1959, 14:133-148
	AEEE	Francis et al., "Ruffles induced by <i>Salmonella</i> and other stimuli direct macropinocytosis of bacteria," <u>Nature</u> , 1993, 364:639-642
	AFFF	Frank et al., "The role of complement in inflammation and phagocytosis," <u>Immun. Today</u> , 1991, 12(9):322-326
	AGGG	Fukami et al., " α -Actinin and Vinculin Are PIP ₂ -binding Proteins Involved in Signaling by Tyrosine Kinase," <u>J. Biol. Chem.</u> , 1994, 269:1518-1522
	AHHH	Gazdar et al., "Characterization of Paired Tumor and Non-Tumor Cell Lines Established from Patients with Breast Cancer," <u>Int. J. Cancer</u> , 1998, 78:766-774
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	AHI	Garcia-del Portillo and Finlay, "Salmonella Invasion of Nonphagocytic Cells Induces Formation of Macropinosomes in the Host Cell," <u>Infect. Immun.</u> , 1994, 62:4641-4645
	AJJJ	Goeddel et al., "Synthesis of human fibroblast interferon by E. coli," <u>Nucl. Acids. Res.</u> , 1980, 8:4057-4074
	AKKK	Grassmé et al., "Gonococcal Opacity Protein Promotes Bacterial Entry-Associated Rearrangements of the Epithelial Cell Actin Cytoskeleton," <u>Infect. Immun.</u> , 1996, 64(5):1621-1630
	ALLL	Griffin, Jr. et al., "Studies on the Mechanism of Phagocytosis: The Interaction of Macrophages with Anti-Immunoglobulin IgG-Coated Bone Marrow-Derived Lymphocytes," <u>J. Exp. Med.</u> , 1976, 144:788-809
	AMMM	Griffin, Jr. et al., "Studies on the Mechanism of Phagocytosis: Requirements for Circumferential Attachment of Particle-Bound Ligands to Specific Receptors on the Macrophage Plasma Membrane," <u>J. Exp. Med.</u> , 1975, 142:1263-1282
	ANNN	Ha and Exton, "Activation of Actin Polymerization by Phosphatidic Acid Derived from Phosphatidylcholine in IIC9 Fibroblasts," <u>J. Cell Biol.</u> , 1993, 123:1789-1796
	AOOO	Harkness, "The Pathology of Gonorrhoea," <u>Br. J. Vener. Dis.</u> , 1948, 24:137-147
	APPP	Harvey et al., "Ultrastructural Analysis of Primary Human Urethral Epithelial Cell Cultures Infected with <i>Neisseria gonorrhoeae</i> ," <u>Infect. Immun.</u> , 1997, 65(6):2420-2427
	AQQQ	Harvey et al., "Receptor-mediated endocytosis of <i>Neisseria gonorrhoeae</i> into primary human urethral epithelial cells: the role of the asialoglycoprotein receptor," <u>Mol. Microbiol.</u> , 2001, 42:659-672
	ARRR	Harvey et al., "Immortalization of Human Urethral Epithelial Cells: a Model for the Study of the Pathogenesis of and the Inflammatory Cytokine Response to <i>Neisseria gonorrhoeae</i> Infection," <u>Infect. Immun.</u> , 2002, 70:5808-5815
	ASSS	Hauck et al., "CD66-mediated-phagocytosis of Opa ₅₂ <i>Neisseria gonorrhoeae</i> requires a Src-like tyrosine kinase- and Rac1-dependent signaling pathway," <u>EMBO J.</u> , 1998, 17:443-454
	ATTT	Hayashi et al., "Binding of the 68-Kilodalton Protein of <i>Mycobacterium avium</i> to $\alpha\beta_3$ on Human Monocyte-Derived Macrophages Enhances Complement Receptor Type 3 Expression," <u>Infect. Immun.</u> , 1997, 65(4):1211-1216
	AUUU	Higgins and Sharp, "CLUSTAL: a package for performing multiple sequence alignment on a microcomputer," <u>Gene</u> , 1988, 73:237-244
	AVVV	Higgins and Sharp, "Fast and sensitive multiple sequence alignments on a microcomputer," <u>CABIOS</u> , 1989, 5:151-153
	AWWW	Hildreth and August, "The Human Lymphocyte Function-Associated (HLFA) Antigen and a Related Macrophage Differentiation Antigen (HMac-1): Functional Effects of Subunit-Specific Monoclonal Antibodies," <u>J. Immunol.</u> , 1985, 134:3272-3280
	AXXX	Hinnebusch et al., "Role of Yersinia Murine Toxin in Survival of <i>Yersinia pestis</i> in the Midgut of the Flea Vector," <u>Science</u> , 2002, 296:733-735
	AYYY	Hodgson et al., "Rational Attenuation of <i>Corynebacterium pseudotuberculosis</i> : Potential Cheesy Gland Vaccine and Live Delivery Vehicle," <u>Infect. Immun.</u> , 1992, 60:2900-2905
	AZZZ	Hondalus et al., "The Intracellular Bacterium <i>Rhodococcus equi</i> Requires Mac-1 To Bind to Mammalian Cells," <u>Infect. Immun.</u> , 1993, 61:2919-2929
	AAAAA	Huang et al., "Parallelization of a local similarity algorithm," <u>CABIOS</u> , 1992, 8:155-165

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	ABBBB	Hussain et al., "Investigation of the complement receptor 3 (CD11b/CD18) in human rectal epithelium," <u>Clin. Exp. Immun.</u> , 1995, 102:384-388
	ACCCC	Hynes, "Integrins: A Family of Cell Surface Receptors," <u>Cell</u> , 1987, 48:549-554
	ADDDD	Iglesias et al., "Interleukin-6 and Interleukin-6 Soluble Receptor Regulate Proliferation of Normal, Human Papillomavirus-Immortalized, and Carcinoma-Derived Cervical Cells <i>In Vitro</i> ," <u>Am. J. Pathol.</u> , 1995, 146:944-952
	AEEEE	Ingalls et al., "The CD11/CD18 Integrins: Characterization of Three Novel LPS Signaling Receptors," <u>Prog. Clin. Biol. Res.</u> , 1998, 397:107-117
	AFFFF	Jarvis et al., "Invasion of Human Mucosal Epithelial Cells by <i>Neisseria gonorrhoeae</i> Upregulates Expression on Intercellular Adhesion Molecule 1 (ICAM-1)," <u>Infect. Immun.</u> , 1999, 67(3):1149-1156
	AGGGG	Jerse and Rest, "Adhesion and invasion by the pathogenic neisseria," <u>Trends in Microbiology</u> , 1997, 5(6):217-221
	AHHHH	Jones et al., "Phospholipase D and membrane traffic: Potential roles in regulated exocytosis, membrane delivery and vesicle budding," <u>Biochim. Biophys. Acta</u> , 1999, 1439:229-234
	AIIII	Jones and Walker, "Integrins: a role as cell signalling molecules," <u>J. Clin. Pathol. Mol. Pathol.</u> , 1999, 52:208-213
	AJJJJ	Jones et al., "Two Signaling Mechanisms for Activation of $\alpha_M\beta_2$ Avidity in Polymorphonuclear Neutrophils," <u>J. Biol. Chem.</u> , 1998, 273(17):10556-10566
	AKKKK	Juriansz et al., "Complement resistance of tumor cells: basal and induced mechanisms," <u>Mol. Immunol.</u> , 1999, 36:929-939
	ALLLL	Källström et al., "Membrane cofactor protein (MCP or CD46) is a cellular pilus receptor for pathogenic <i>Neisseria</i> ," <u>Mol. Microbiol.</u> , 1997, 25:639-647
	AMMMM	Källström et al., "Cholera toxin and extracellular Ca^{2+} induce adherence of non-piliated <i>Neisseria</i> : evidence for an important role of G-proteins and Rho in the bacteria-cell interaction," <u>Cell Microbiol.</u> , 2000, 2:341-351
	ANNNN	Karlin and Altschul, "Methods for assessing the statistical significance of molecular sequence features by using general scoring schemes," <u>Proc. Natl. Acad. Sci. USA</u> , 1990, 87:2264-2268
	AOOOO	Karlin and Altschul, "Applications and statistics for multiple high-scoring segments in molecular sequences," <u>Proc. Natl. Acad. Sci. USA</u> , 1993, 90:5873-5877
	APPPP	Kaur and McDougall, "Characterization of Primary Human Keratinocytes Transformed by Human Papillomavirus Type 18," <u>J. Virol.</u> , 1988, 62:1917-1924
	AQQQQ	Ketterer et al., "Infection of Primary Human Bronchial Epithelial Cells by <i>Haemophilus influenzae</i> : Macropinocytosis as a Mechanism of Airway Epithelial Cell Entry," <u>Infect. Immun.</u> , 1999, 4161-4170
	ARRRR	Kishimoto et al., "The Leukocyte Integrins," <u>Advances in Immunology</u> , 1989, 46:149-182
	ASSSS	Köhler et al., "Continuous cultures of fused cells secreting antibody of predefined specificity," <u>Nature</u> , 1975, 256:495
	ATTTT	Kondo et al., "Phospholipase D Mimics Platelet-derived Growth Factor as a Competence Factor in Vascular Smooth Muscle Cells," <u>J. Biol. Chem.</u> , 1992, 267:23609-23616

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	AUUUU	Kondo et al., "Two-dimensional electrophoretic studies on down-regulated intracellular transferrin in human fibroblasts immortalized by treatment with either 4-nitroquinoline 1-oxide or ⁶⁰ Co gamma rays," <u>Electrophoresis</u> , 1996, 17:1638-1642
	AVVVV	Kragstjerg et al., "The effects of live <i>Neisseria meningitidis</i> and tumour necrosis factor- α on neutrophil oxidative burst and β 2-integrin expression," <u>APMIS</u> , 2000, 108:276-282
	AWWWW	Kunkel, "Rapid and efficient site-specific mutagenesis without phenotypic selection," <u>Proc. Natl. Acad. Sci. USA</u> , 1985, 82:488-492
	AXXXX	Kunkel et al., "Rapid and Efficient Site-Specific Mutagenesis without Phenotypic Selection," <u>Meth. Enzymol.</u> , 1987, 154:367-382
	AYYYY	Kusner et al., "Regulation of Phospholipase D Activity by Actin: Actin Exerts Bidirectional Modulation of Mammalian Phospholipase D Activity in a Polymerization-Dependent, Isoform-Specific Manner," <u>J. Biol. Chem.</u> , 2002, 277:50683-50692
	AZZZZ	Kusner et al., "Evolutionary conservation of physical and functional interactions between phospholipase D and actin," <u>Arch. Biochem. Biophys.</u> , 2003, 412:231-241
	AAAAAA	Lawn et al., "The sequence of human serum albumin cDNA and its expression in <i>E. coli</i> ," <u>Nucl. Acids. Res.</u> , 1981, 9:6103-6114
	ABBBBB	Lehninger, "The amino acid building blocks of proteins," <u>Biochemistry</u> , 2 nd ed., 1975, 73-75
	ACCCCC	Lin et al., "Increased Expression of Luteinizing Hormone/Human Chorionic Gonadotropin Receptor Gene in Human Endometrial Carcinomas," <u>J. Clin. Endocrinol. Metab.</u> , 1994, 79:1483-1491
	ADDDDD	Lukowski et al., "Inhibition of Phospholipase D Activity by Fodrin: An Active Role for the Cytoskeleton," <u>J. Biol. Chem.</u> , 1996, 271:24164-24171
	AEEEEEE	Lynch et al., "Studies of Porins: Spontaneously Transferred from Whole Cells and Reconstituted from Purified Proteins of <i>Neisseria gonorrhoeae</i> and <i>Neisseria meningitidis</i> ," <u>Biophys. J.</u> , 1984, 45:104-107
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	AGGGGG	Maitra et al., "Enrichment of epithelial cells for molecular studies," <u>Nature Med.</u> , 1999, 5:459-463
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Other Documents (include Author, Title, Date, and Place of Publication)		
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	AQQQQC	Moll et al., "The Catalog of Human Cytokeratins: Patterns of Expression in Normal Epithelia, Tumors and Cultured Cells," <u>Cell</u> , 1982, 31:11-24
	ARRRRR	Morse and Bartenstein, "Purine metabolism in <i>Neisseria gonorrhoeae</i> : the requirement for hypoxanthine," <u>Can. J. Microbiol.</u> , 1980, 26:13-20
	ASSSSS	Mosser and Edelson, "The third component of complement (C3) is responsible for the intracellular survival of <i>Leishmania major</i> ," <u>Nature</u> , 1987, 327:329-331
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	AUUUUU	Mukherjee et al., "Endocytosis," <u>Physiol. Rev.</u> , 1997, 77:759-803
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	AWWWWW	Nassif and So., "Interaction of Pathogenic Neisseriae with Nonphagocytic Cells," <u>Clin. Microbiol. Rev.</u> , 1995, 8:376-388
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	AFFFFFF	Pearson and Lipman, "Improved tools for biological sequence comparison," <u>Proc. Natl. Acad. Sci. USA</u> , 1988, 85:2444-2448
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	FFFFFF	Smith and Waterman, "Comparison of Biosequences," <u>Adv. Appl. Math.</u> , 1981, 2:482-489
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	NNNNNN	Sun et al., "In Vivo Cytokeratin-Expression Pattern of Stratified Squamous Epithelium from Human Papillomavirus-Type-16-Immortalized Ectocervical and Foreskin Keratinocytes," <u>Int. J. Cancer</u> , 1993, 54:656-662
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